



## **Agricultural Marketing Service**

### **7 CFR Part 205**

**[Doc. No. AMS-NOP-21-0060]**

**RIN 0581-AE11**

## **Amendments to the National List of Allowed and Prohibited Substances per October 2020 and April 2021 NOSB Recommendations (Handling, Crops)**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture’s (USDA) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule allows low-acyl gellan gum, a food additive used as a thickener, gelling agent, and stabilizer, as an ingredient in processed organic products. This rule also allows paper-based crop planting aids for organic crop production. Finally, this rule replaces the term “wood resin” on the National List with the term “wood rosin” to reflect the popular spelling of the substance.

**DATES:** This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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### **SUPPLEMENTARY INFORMATION:**

#### **Background**

On December 21, 2000, the Secretary established the Agricultural Marketing Service’s (AMS) National Organic Program (NOP) and the USDA organic regulations (65 FR 80547, December 21, 2000). Within the USDA organic regulations

(7 CFR part 205) is the National List of Allowed and Prohibited Substances (or “National List”). The National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic crop and livestock production. It also identifies the nonorganic substances that may be used in or on processed organic products.

AMS is finalizing three amendments to the National List in accordance with the procedures detailed in the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6524). OFPA establishes what may be included on the National List and the procedures that the USDA must follow to amend the National List (7 U.S.C. 6517). OFPA also describes the NOSB’s responsibilities in proposing amendments to the National List, including the criteria for evaluating amendments to the National List (7 U.S.C. 6518).

According to OFPA’s requirements, substances on the National List must be: (1) reviewed every five years by the NOSB, a 15-member Federal advisory committee; and (2) renewed by the Secretary to remain on the National List (7 U.S.C. 6517(e)). This action of NOSB review and USDA renewal is commonly referred to as the “sunset review” or “sunset process.” AMS published information about this process in the **Federal Register** on September 16, 2013 (78 FR 56811). The sunset date (*i.e.*, the date by which the Secretary must renew a substance for the listing to remain valid on the National List) for each substance is included in the NOP Program Handbook (document NOP 5611). The sunset date for the two substances added to the National List by this rule will be five years after the effective date noted in the **DATES** section above. The sunset date for wood rosin is unchanged by this rule and remains March 15, 2027 (86 FR 41699, August 3, 2021).

## **Overview of Amendments**

This rule adds low-acyl gellan gum and paper-based crop planting aids to the National List. This rule also adds a definition for “paper-based crop planting aids” to 7 CFR 205.2. Once this rule becomes effective, organic crop producers and organic handlers will be allowed to use these substances in organic crop production and handling, as applicable. The permitted use of each substance is discussed in detail below. This rule also replaces the term “wood resin” at 7 CFR 205.605(a) with the term “wood rosin” to reflect the popular spelling of the substance. Additional background on the petitions and on the NOSB’s review of these substances may be found in the proposed rule (87 FR 5424, February 1, 2022).

During a 60-day comment period that closed on April 4, 2022, AMS received 45 comments on the proposed rule. See below for a discussion of the comments received and AMS’s responses to comments. Comments can be viewed at *Regulations.gov*. Use the search area on the homepage at <https://www.regulations.gov> to enter a keyword, title, or docket ID (the docket ID for this rule is AMS-NOP-21-0060).

#### **A. Low-Acyl Gellan Gum (§ 205.605(b))**

*Section 205.605(b) Nonagricultural synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”*

##### ***Overview***

This rule amends the National List to add low-acyl gellan gum to 7 CFR 205.605(b) as a nonagricultural, synthetic substance allowed for use in organic handling as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” Low-acyl gellan gum is a polysaccharide (type of carbohydrate) produced through fermentation (from the microorganism *Sphingomonas elodea*). It is manufactured from high-acyl gellan gum, a substance allowed in organic production, which is isolated from microbial fermentation.

Low-acyl gellan gum is used in a wide variety of food products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring such as ready-to-eat dessert gels, icings, and beverages.

AMS is finalizing this amendment to the National List, as recommended by the NOSB after its October 2020 public meeting,<sup>1</sup> to provide organic handlers an ingredient for thickening, gelling, and stabilizing. Synthetic low-acyl gellan gum is made from natural high-acyl gellan gum, which is already allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (§ 205.605(a)).

Low-acyl gellan gum holds unique qualities not found in other thickener substances on the National List (*e.g.*, high-acyl gellan gum, carrageenan). While high-acyl gellan gum produces gels that are soft, elastic, and non-brittle, low-acyl gellan gum can be used to create a firmer, harder, and non-elastic gel. Food producers can vary the ratios of both high- and low-acyl gellan gums to produce different textures. Low-acyl gellan gum can also be used to increase viscosity of beverages or be used to suspend matter in beverages, such as those containing fruit pulp or jelly pieces. Additionally, low-acyl gellan gums can be clarified to create a gel with better clarity than other gums—important for certain confectionary applications such as icings and fillings. Gellan gums can better withstand higher temperatures while maintaining their gel form than other gelling agents, such as gelatin, can. Additionally, low-acyl gellan gum can be used in standard processing without additional steps (*e.g.*, compared to pectin, which requires special handling in gelled confections). Finally, low-acyl gellan gum provides a vegetarian alternative to gelatin in hard and soft capsules used for products such as dietary supplements.

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<sup>1</sup> National Organic Standards Board, formal recommendation, low-acyl gellan gum, October 30, 2020, [https://www.ams.usda.gov/sites/default/files/media/HSLowAcylGellanGumRec\\_webpost.pdf](https://www.ams.usda.gov/sites/default/files/media/HSLowAcylGellanGumRec_webpost.pdf).

## ***NOSB Review and Recommendation***

Following review of an August 2019 petition,<sup>2,3</sup> the NOSB recommended that low-acyl gellan gum be added to the National List.<sup>1</sup> The NOSB's evaluation of low-acyl gellan gum considered comments from the public, a previously commissioned third-party technical report on gums,<sup>4</sup> and the petition itself. The NOSB discussed this petition in subcommittee calls and at its public meeting in October 2020.<sup>5</sup>

After their evaluation, the NOSB concluded that adding low-acyl gellan gum to the National List is consistent with the evaluation criteria in OFPA (7 U.S.C. 6518(m)). The NOSB concluded that low-acyl gellan gum has minimal adverse effects on the environment and human health. Additionally, the NOSB acknowledged the distinct properties of low-acyl gellan gum and noted that it can be used to manufacture hard, non-elastic, brittle gels (unlike high-acyl gellan gum). This property allows it to be used in the production of capsules used for dietary supplements. Notably, its allowance by this rule will give organic handlers an alternative to gelatin to produce vegetarian and vegan products—an important attribute for a segment of consumers.

The NOSB recommended that low-acyl gellan gum be classified as “synthetic”. As defined by OFPA and the USDA organic regulations, a synthetic substance is produced by a chemical process, or by a process that chemically changes a natural substance (7 U.S.C. 6502(22) and 7 CFR 205.2). As the manufacturing process for low-

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<sup>2</sup> Petition for Evaluation of Low Acyl Gellan Gum for Inclusion on the National List of Substances Allowed in Organic Production and Handling (7 CFR 205.605(b), CP Kelco U.S., Inc., National List Petition, August 8, 2019, <https://www.ams.usda.gov/sites/default/files/media/PetitionLowAcylGellanGum08082019.pdf>.

<sup>3</sup> Response To Request For Information Low Acyl Gellan Gum, CP Kelco U.S., Inc., National List Petition Update, March 6, 2020, [https://www.ams.usda.gov/sites/default/files/media/PetitionAddendum\\_LAGellanGum\\_ResponsetoNOSB\\_03062020.pdf](https://www.ams.usda.gov/sites/default/files/media/PetitionAddendum_LAGellanGum_ResponsetoNOSB_03062020.pdf).

<sup>4</sup> National Organic Program, Gums, Nexight Group, technical report, January 30, 2018, <https://www.ams.usda.gov/sites/default/files/media/GumsTRFinal20180130.pdf>.

<sup>5</sup> National Organic Standards Board (NOSB) Meeting – Virtual, National Organic Standards Board, October 28, 2020, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-cedar-rapids-iowa>.

acyl gellan gum includes the deacetylation of high-acyl gellan gum (reducing the number of acetyl groups<sup>6</sup> by adding potassium, magnesium, calcium, and/or sodium salts), which is considered a chemical change, the NOSB determined this is a synthetic substance.

### ***Comments Received and AMS Responses***

AMS received 16 comments in response to the proposed listing of low-acyl gellan gum from a diverse audience, including: certified operations, certifying agents, trade groups, substance manufacturers, and the public. The subjects of these comments and responses from AMS are covered in this section. AMS is finalizing the addition of low-acyl gellan gum as drafted in the proposed rule.

The majority of commenters were in favor of adding low-acyl gellan gum to the National List and agreed with the NOSB's recommendation. Commenters supported the addition based on the absence of evidence that low-acyl gellan gum is harmful to human health or the environment and based on the FDA allowance of low-acyl gellan gum as a food additive. Additionally, commenters stated this substance is necessary and would support market development of organic products, due to the lack of wholly natural thickeners with similar properties.

A few comments were opposed to the addition of the substance to the National List. Two commenters expressed concern that a manufacturer of low-acyl gellan gum petitioned for the addition to the National List and stood to benefit from inclusion of the substance. Another commenter was opposed due to the processed nature of the substance.

AMS notes that the National List is an optional list of generic substances that an operation may use in their products. Petitions to amend the National List may be submitted by any person, and substances on the National List may be produced by any

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<sup>6</sup> The number of acetyl groups determines the firmness of the gel. An acetyl group is a molecule made up of a methyl group single-bonded to a carbonyl (CH<sub>3</sub>CO).

manufacturer. Furthermore, OFPA expressly permits nonorganic ingredients in organic handling, including synthetic ingredients included on the National List for use in organic processed products. These individual synthetic ingredients must meet the criteria in OFPA (*e.g.*, not harmful to human health and the environment), as evaluated by the NOSB and AMS, and undergo rulemaking to add them to the National List. The NOSB and AMS evaluated low-acyl gellan gum and determined that it met the statutory requirements for addition to the National List.

Some commenters misperceived the proposed rule as allowing low-acyl gellan gum for use by farmers in organic crop production. AMS does not respond to these comments, as the rule does not allow low-acyl gellan gum in crop production. The rule allows use of low-acyl gellan gum in organic handling (*i.e.*, processing). One of these commenters expressed concern with negative health effects associated with overconsumption of gellan gum and mentioned an unnamed animal study.

After review of the comment, AMS concluded that allowance of low-acyl gellan gum is not likely to be harmful to human health. First, gellan gum is listed by the Food & Drug Administration (FDA) as a safe food additive permitted for direct addition to food for human consumption at 21 CFR 172.665. The FDA requires prescribed conditions for its safe use, including following good manufacturing practices (21 CFR 172.665(e)). Additionally, the rule only allows limited use of low-acyl gellan gum, as allowed synthetic substances cannot be used at levels greater than 5 percent (by weight or fluid volume, excluding water and salt) in products labeled “organic” (§ 205.301(b)). As a food additive, low-acyl gellan gum will be used to thicken, gel, and stabilize processed organic products.

### ***AMS Review***

As described in the BACKGROUND section, OFPA establishes what may be included on the National List and the procedures that AMS must follow to amend the

National List. As directed by OFPA, AMS must show that a substance: is not harmful to human health or the environment; is necessary for handling because of the unavailability of wholly natural substitute products; and is consistent with organic handling. OFPA also describes the NOSB's responsibilities in recommending amendments to the National List, including evaluation criteria.

First, AMS agrees with the classification of low-acyl gellan gum as a "synthetic" substance, as the process of removing acetyl groups by deacetylation fits the definition of "synthetic" at 7 CFR 205.2 and 7 U.S.C. 6502 and as described in AMS published guidance on the classification of materials.<sup>7</sup>

AMS also concludes that the addition of low-acyl gellan gum to the National List is consistent with the requirements of OFPA (7 U.S.C. 6517(c)(1)(A)). While NOSB determined that low-acyl gellan gum had minimal adverse effects on the environment and human health, AMS determined there is no impact. First, low-acyl gellan gum is not harmful to human health or the environment, as gellan gum is listed by the Food & Drug Administration (FDA) as a food additive permitted for direct addition to food for human consumption at 21 CFR 172.665. Additionally, gellan gum is allowed as an inert ingredient in minimum risk pesticides (*i.e.*, pesticide products exempt from the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)) by the U.S. Environmental Protection Agency (EPA) at 40 CFR 152.25(f)(2)(iv)). Second, low-acyl gellan gum is necessary because of the absence of wholly natural substitute products, as evidenced by public comment submitted to the NOSB and as reported in the 2018 technical report. Finally, the use of low-acyl gellan gum is consistent with organic handling. This amendment follows the NOSB recommendation according to the procedures established in OFPA (7 U.S.C. 6517(d)).

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<sup>7</sup> National Organic Program, NOP 5033 Classification of Materials, guidance, December 2, 2016, <https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf>.



## **B. Paper-Based Crop Planting Aids (§ 205.601(o)(2))**

*Section 205.601(o) Synthetic production aids allowed for use in organic crop production*

### ***Overview***

This rule amends the National List to add paper-based crop planting aids to 7 CFR 205.601 as a synthetic substance allowed for use in organic crop production. This rule also adds a definition for paper-based crop planting aids to the USDA organic regulations (§ 205.2, *Terms defined*). Together, these amendments allow use of paper-based crop planting aids, including those that are placed in or on the soil and later incorporated into the soil.

AMS is finalizing this amendment to the National List, as recommended by the NOSB after its April 2021 meeting,<sup>8</sup> to provide certified operations an additional tool for planting or transplanting crops. Paper-based crop planting aids (*e.g.*, individual pots, chain pots, seed tape, collars) provide an alternative to the slower and more costly method of planting or transplanting individual crops by hand.

### ***NOSB Review and Recommendation***

Following review of a petition submitted in August 2018,<sup>9,10</sup> the NOSB recommended adding paper-based crop planting aids to the National List and recommended a regulatory definition of these products.<sup>8</sup> In their evaluation of paper-based crop planting aids, the NOSB considered comments from the public, a commissioned technical report on paper-pots and containers,<sup>11</sup> previously commissioned

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<sup>8</sup> National Organic Standards Board, Formal Recommendation, paper-based crop planting aids, April 30, 2021, [https://www.ams.usda.gov/sites/default/files/media/CSPaperBasedCropPlantingAids\\_FinalRec.pdf](https://www.ams.usda.gov/sites/default/files/media/CSPaperBasedCropPlantingAids_FinalRec.pdf).

<sup>9</sup> Petition for hemp paper or other paper, without glossy or colored inks, as a plant pot or growing container, Small Farm Works, National List Petition, August 7, 2018, <https://www.ams.usda.gov/sites/default/files/media/PaperPotorContainerPetition080718.pdf>.

<sup>10</sup> Petition Addendum Regarding Paper Pot Adhesives, Small Farm Works, National List Petition, October 2, 2018, <https://www.ams.usda.gov/sites/default/files/media/PetitionAddendumPaperPots10022018.pdf>.

<sup>11</sup> National Organic Program, Paper Pots and Containers, Nexight Group and Organic Materials Review Institute, technical report, July 26, 2019, <https://www.ams.usda.gov/sites/default/files/media/PaperTRFinal7262019.pdf>.

technical reports on newspaper,<sup>12,13</sup> and the petition itself. The NOSB discussed the petition to amend the National List in subcommittee calls and at its public meetings in October 2018,<sup>14</sup> April and October 2019,<sup>15,16</sup> April and October 2020,<sup>17,5</sup> and April 2021.<sup>18</sup>

After their evaluation, the NOSB concluded that adding paper-based crop planting aids to the National List is consistent with evaluation criteria in OFPA (7 U.S.C. 6518(m)). The NOSB found that the use of paper-based crop planting aids is compatible with organic crop production and provides benefits compared to planting or transplanting crops by hand. The NOSB recommended classifying paper-based crop planting aids as “synthetic” due to the manufacturing process. As defined by OFPA and the USDA organic regulations, a synthetic substance is produced by a chemical process or by a process that chemically changes a natural substance (7 U.S.C. 6502(22) and 7 CFR 205.2). Manufacturing paper includes breaking down wood chips into paper pulp through either acidic or alkaline chemical reactions, so it meets this definition of “synthetic”. Additionally, paper is classified as synthetic for other uses on the National List (§ 205.601).

### ***Comments Received and AMS Responses***

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<sup>12</sup> National Organic Program, Newspaper or Other Recycled Paper, ICF Consulting, technical report, January 27, 2006, <https://www.ams.usda.gov/sites/default/files/media/Newspaper%20TR%202006.pdf>.

<sup>13</sup> National Organic Program, Newspaper or Other Recycled Paper, Organic Materials Review Institute, technical report, January 11, 2017, <https://www.ams.usda.gov/sites/default/files/media/Newspaper%20TR%20Final%2001%2011%2017.pdf>.

<sup>14</sup> National Organic Standards Board (NOSB) Meeting – St. Paul, MN, National Organic Standards Board, October 24, 2018, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-st-paul-mn>.

<sup>15</sup> National Organic Standards Board (NOSB) Meeting – Seattle, WA, National Organic Standards Board, April 24, 2019, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>.

<sup>16</sup> National Organic Standards Board (NOSB) Meeting – Pittsburgh, PA, National Organic Standards Board, October 23, 2019, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-pittsburgh-pa>.

<sup>17</sup> National Organic Standards Board (NOSB) Meeting – Virtual, National Organic Standards Board, April 29, 2020, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-crystal-city-va>.

<sup>18</sup> National Organic Standards Board (NOSB) Meeting - Virtual, National Organic Standards Board, April 28, 2021, <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-crystal-city-va-0>.

AMS received 38 comments in response to the proposed listing of paper-based crop planting aids. Most comments supported the addition of paper-based crop planting aids for organic crop production to the National List. Many comments were from certified organic operations. Commenters supported the use of paper-based crop planting aids on account of improved efficiency in transplanting crops. Commenters indicated that these products would allow smaller operations to exponentially increase planting efficiency and save money on labor while retaining organic certification. Many commenters also cited the environmental benefit of reduced plastic waste, as paper-based crop planting aids could replace plastic seedling trays and pots.

The subjects of public comments and responses from AMS are described below. The rule makes minor modifications to the definition of “paper-based crop planting aids” (§ 205.2) and to introductory language in the National List (§ 205.601) to clarify the intent and meaning of the amendments. These comments and changes are discussed below.

Several commenters, including certifying agents, material review organizations, and trade groups, recommended removal of the last sentence in the proposed definition for “paper-based crop planting aids”: “Added nutrients must comply with §§ 205.105, 205.203, and 205.206.”. The commenters indicated that the statement was unclear, inaccurate, and/or unnecessary. They indicated that certified organic crop operations are already required to comply with overarching requirements in the USDA organic regulations related to allowed and prohibited substances, methods, and ingredients (§ 205.105) as well as requirements related to soil fertility and crop nutrient management (§ 205.203). They argued that references to these sections of the USDA organic regulations would therefore be redundant. Commenters also indicated that the reference to crop pest, weed, and disease management practice standards (§ 205.206) would be inappropriate because that section of the regulations does not relate to “nutrients”.

AMS agrees with the commenters that the references to §§ 205.105, 205.203 and 205.206 within the definition of “paper-based crop planting aid” are unnecessary. Sections 205.105 and 205.203 apply to all certified organic crop operations, and reference to the crop pest, weed, and disease management practice standards (§ 205.206) is not relevant or necessary to the definition. AMS has modified the definition of “paper-based crop planting aid” in this rule to remove these references from the definition.

One commenter suggested an update to the regulatory text found in the introduction to the crop substances section of the National List (§ 205.601). The current language here exempts certain categories of synthetic substances on the National List from certain provisions of the USDA organic regulations, specifically, the requirements to first use crop pest, weed, and disease preventive practices and nonsynthetic substances prior to the use of synthetic substances on the National List. For example, synthetic compost feedstocks, plant and soil amendments, plant growth regulators, and floating agents used in postharvest handling, are currently allowed in organic crop production without regard to these preventive practices. The commenter suggested that AMS update the language to clarify that crop production aids, including paper-based crop planting aids, may also be used without regard to those preventive practices. A commenter also suggested that AMS should clarify that fatty alcohols containing allowed synthetic inert ingredients (§ 205.601(m)) are similarly exempt.

AMS agrees that the introductory text at § 205.601 should be updated to include crop production aids as exempt from the provisions set forth in § 205.206(a) through (d). Crop production aids specifically included at § 205.601(o) may be used by producers without first considering other alternative practices or nonsynthetic substances for preventing crop pests, weeds, and diseases. For example, paper-based chain pots are used to transplant seedlings into a field. It would be confusing and impractical for the USDA organic regulations to first require the use of transplanting by hand, or first require

the use of nonsynthetic substances, prior to allowing use of paper-based chain pots. The rule updates the introductory text for this section of the National List (the specific modifications to the regulatory text can be found at the bottom of this document). AMS is not updating the text to address the comment related to fatty alcohols containing inert ingredients, as the substance was not included or discussed as part of the proposed rule. AMS may consider additional changes to the introductory text for this section of the National List in a future proposed rule.

In the proposed rule, AMS specifically requested public comment on the interpretation of the wording in the proposed definition that references the qualifications of people tasked with determining the biobased content of these products. As discussed in the proposed rule, AMS interprets “qualified personnel” to be a third-party (*i.e.*, certifying agent or material review organization, see NOP Program Handbook NOP 3012 “Material Review – Interim Instruction”<sup>19</sup>) capable and qualified to make limited biobased determinations. AMS stated that if the biobased nature of the ingredients were clear (*e.g.*, a product composed entirely of paper and coconut coir), then the review of the product could be performed by qualified personnel without a laboratory test (ASTM D6866). A discussion of comments received on this topic follows. The rule makes no changes related to “qualified personnel”.

Several commenters, including certifying agents, material review organizations, and trade groups, agreed that “qualified personnel” would include certifying agents and material review organizations. Of these commenters, a certifying agent and material review organization expressed confidence in their ability to evaluate the biobased content of some paper-based crop planting aids outside of an ASTM D6866 laboratory result. Several paper-based crop planting aid manufacturers also submitted comments. These

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<sup>19</sup> National Organic Program, NOP 3012 Material Review, Interim Instruction, August 30, 2016, <https://www.ams.usda.gov/sites/default/files/media/NOP%203012%20Material%20Review.pdf>.

manufacturers indicated that they currently produce products that meet the composition requirements. Some stated that they plan to work with a material review organization to verify compliance with the USDA organic regulations following publication of this rule.

One commenter, a certifying agent, expressed concern that the definition lacked clarification on what constitutes “qualified personnel”. This commenter also expressed overall concerns with the composition requirements. The commenter stated that they deviate significantly from current industry standards and practices, as no products currently available cite third-party standards or provide detailed information on the percentage of biobased or cellulose content. This commenter indicated that the detailed requirements regarding cellulose and biobased content would require both product manufacturers and certifying agents to perform multiple calculations, demanding more time and expense of certifying agents without affording significant tangible benefits to organic integrity. This commenter requested that AMS clearly set out minimum qualifications to meet the definition of “qualified personnel” and specify methods to be used to determine biobased content outside of an ASTM D6866 laboratory result.

AMS appreciates the public comments in response to AMS’s questions set forth in the proposed rule. AMS is not making additional changes from the proposed rule in this rule regarding “qualified personnel”. Formulation review of products composed of allowed substances is a common practice among certifiers and material review organizations to ensure that products are compliant with the USDA organic regulations. If the biobased nature of the ingredients is unclear, then the composition of the product should be determined by a laboratory test (ASTM D6866). AMS expects much of the paper-based crop planting aids review process to fit into current product formulation evaluation processes and via the ASTM D6866 standard. AMS encourages certifying agents and material review organizations and other qualified third parties to consult

guidance previously set forth by AMS, which encourages certifying agents to consult with each other regarding material review.<sup>19</sup>

One commenter expressed concern with specific reference to only synthetic substances allowed as plant or soil amendments—on the National List at § 205.601(j))—in the definition of “paper-based crop planting aids.” This commenter suggested that it is not necessary to refer to these substances because material reviewers should review added ingredients against the relevant subsection of the National List.

AMS disagrees with the suggestion to remove reference to synthetic substances allowed as plant and soil amendments (§ 205.601(j)) from the definition, thereby allowing the inclusion of any synthetic substances on the National List for organic crop production. The rule aligns with the NOSB’s recommendation on this topic. During the development of their recommendation, the NOSB considered whether the non-cellulose content of these products could include synthetic pest and disease control substances from the National List. The NOSB discarded this option, stating, for example, that pesticides embedded in these products could have adverse impacts on biodiversity.

AMS agrees that organic producers may only use synthetic substances on the National List for crop pest, weed, and disease control when other practices (see § 205.206) are insufficient to prevent or control crop pests, weeds, and diseases. The rule does not allow synthetic pesticides in paper-based crop planting aids, as inclusion of these substances would likely lead to prophylactic use of synthetic substance(s). The use of synthetic substances in this manner is not permitted by the USDA organic regulations (§ 205.206(e)).

In accordance with the NOSB recommendation, the rule only permits the addition of the following synthetic substances in paper-based crop planting aids: substances on the National List in § 205.601(j) as plant and soil amendments; and ingredients used in strengthening fibers, adhesives, or resins.

One commenter opposed the allowance of synthetic strengthening fibers, adhesives, and resins in the definition of paper-based crop planting aids. The commenter indicated that the synthetic allowances are unnecessary and that the proposed composition requirements would not drive manufacturers to develop products with fewer synthetic ingredients. They indicated that a pot, made from only paper, could be dipped in natural rubber and yield the same labor-saving advantages as the proposed paper-based crop planting aids.

AMS disagrees with prohibiting synthetic strengthening fibers, adhesives, and resins. First, as outlined in the OVERVIEW section, paper-based crop planting aids include not only individual pots but also products such as chain pots, seed tape, and collars. Second, paper-based crop planting aids require strengthening additives to increase “wet strength” so that they will not breakdown prior to transplanting. These additional synthetic substances allow paper-based crop planting aids to hold their structure and resist breakdown in the presence of water, soil media, and plant roots.<sup>11</sup>

One commenter urged AMS to update the reference to the ASTM standard ASTM D6866 in future rulemaking, as incorporated into the USDA organic regulations by reference (see § 205.3, *Incorporation by reference*). They also urged AMS to include regular review of the incorporated references listed in § 205.3, such as when National List substances go through the sunset review process.

AMS recognizes that the standards incorporated into the USDA organic regulations by reference are subject to change over time, and AMS understands a newer version of the ASTM D6866 standard has been adopted by ASTM (currently ASTM D6866-22, adopted in 2022 compared to ASTM D6866-12 referenced in the USDA organic regulations and adopted in 2012). AMS intends to update the reference to ASTM D6866-12 and to other references (§ 205.3) in future rulemaking.

***AMS Review***



AMS concludes that adding paper-based crop planting aids to the National List is consistent with the requirements of OFPA (7 U.S.C. 6517(c)(1)(A)), and this amendment adopts the NOSB recommendation according to OFPA procedures (7 U.S.C. 6517(d)). Paper-based crop planting aids appear to be necessary due to the lack of wholly nonsynthetic (natural) substitute products. Additionally, paper-based crop planting aids are expected to readily break down in the soil and do not appear to be harmful to human health or the environment when used for crop planting or transplanting purposes. This conclusion is supported by the presence of paper on EPA's list of "inert ingredients permitted in minimum risk pesticide products" at 40 CFR 152.25(f)(2)(iv). Furthermore, the addition of paper for these uses is consistent with the other allowed uses of paper under the USDA organic regulations, namely, as a mulch (7 CFR 205.601(b)(2)(i)) and compost feedstock (§ 205.601(c)). AMS also notes and agrees with comments that allowance of paper-based crop planting aids could reduce use of plastic, thereby providing an environmental benefit.

Finally, AMS agrees with the NOSB's classification of paper-based crop planting aids as a "synthetic" substance, as the acid-base reactions included in the kraft process of manufacturing paper, as well as the inclusion of additional synthetic substances to improve performance, fit the definition of "synthetic" as described in the USDA organic regulations (7 CFR 205.2) and AMS published guidance on the classification of materials.<sup>7</sup>

### **C. Wood Rosin (sic. Resin; § 205.605(a))**

*Section 205.605(a) Nonagricultural nonsynthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."*

### **Overview**

This rule amends the National List to update the spelling of “wood resin” to “wood rosin” in the definition of “waxes” at 7 CFR 205.605(a).

### ***NOSB Review and Recommendation***

Following the 2022 sunset review for wood resin, the NOSB recommended a correction to the spelling of “wood resin” (to “wood rosin”) on the National List. “Wood resin” is currently included on the National List as an allowed nonorganic substance in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”<sup>20</sup> The NOSB stated in this recommendation that “wood rosin” is the more accurate and current spelling and that AMS should replace the word “resin” with “rosin”. The NOSB discussed the recommendation for this technical correction in subcommittee calls and at its public meeting in October 2020.<sup>5</sup>

### ***AMS Review and Comments Received***

AMS concludes that “resin” can also refer to “rosin”—as noted by AMS in a 1997 proposed rule (62 FR 65850, December 16, 1997)—but AMS agrees “rosin” is the preferred term because it is more specific to the wood product and aligns more closely with the use of the term in the market. Additionally, the spelling “rosin” more closely aligns with FDA (21 CFR 178.3870, *Rosins and rosin derivatives*) and World Health Organization definitions for food-grade rosin.<sup>21</sup> AMS does not expect this spelling modification to have any impact on organic handlers.

AMS received six comments in response to the proposed technical correction of “wood resin” to “wood rosin”. All public submissions supported the correction. The rule replaces the term “Wood resin” with “Wood rosin” at 7 CFR 205.605(a).

### ***Related Documents***

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<sup>20</sup> National Organic Standards Board, formal recommendation, handling 2022 sunset reviews, October 30, 2020, [https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs\\_webpost.pdf](https://www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf).

<sup>21</sup> Joint FAO/WHO Expert Committee on Food Additives. (1975). *Toxicological Evaluation of Some Food Colours, Enzymes, Flavour Enhancers, Thickening Agents, and Certain Food Additives* (No. 6). World Health Organization.

AMS published notices in the **Federal Register** announcing the Fall 2020 NOSB Meeting (85 FR 54343, September 1, 2020) and announcing the Spring 2021 NOSB meeting (86 FR 10161, February 18, 2021). These notices invited public comments on the NOSB recommendations addressed in this rule. The AMS proposed rule, which preceded this rule, was published on February 1, 2022 (87 FR 5424).

### **Statutory and Regulatory Authority**

OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. OFPA authorizes the NOSB to develop recommendations for submission to the Secretary to amend the National List and to establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List (7 U.S.C 6518(k) and (n)). Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA (7 CFR 205.607). The current petition procedures published in the **Federal Register** (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the AMS website at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

### **Executive Orders 12866 and 13563 and the Regulatory Flexibility Act**

This rule does not meet the criteria of a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Therefore, the Office of Management and Budget (OMB) has not reviewed this rule under those orders.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action.

Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.<sup>22</sup> The SBA classifies small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$2 million (13 CFR 121.201). Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector “all other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$17 million.

*Producers.* AMS has considered the economic impact of this rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2019 Certified Organic Survey, 16,524 organic farms in the United States reported total sales of organic products and total farmgate sales more than \$9.9 billion.<sup>23</sup> Based on that data, organic sales average \$601,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$2 million sales threshold to qualify as a small business.

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<sup>22</sup> U.S. Small Business Administration (SBA), Table of Small Business Size Standards Matched to North American Industry Classification System Codes, May 2, 2022, <https://www.sba.gov/document/support-table-size-standards>.

<sup>23</sup> USDA, National Agricultural Statistics Service (NASS), 2017 Census of Agriculture, Volume 1, Chapter 1 US, [https://www.nass.usda.gov/Publications/AgCensus/2017/Full\\_Report/Volume\\_1,\\_Chapter\\_1\\_US/](https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/).

*Handlers.* According to the NOP’s Organic Integrity Database (OID), there are 10,896 U.S.-based organic handlers that are certified under the USDA organic regulations.<sup>24</sup> The Organic Trade Association’s 2021 Organic Industry Survey has information about employment trends among organic manufacturers.<sup>25</sup> The reported data are stratified into three groups by the number of employees per company: fewer than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector, and the lower bound (50) of the range for the larger manufacturers is notably smaller than the SBA’s small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

*Certifying agents.* The SBA defines “all other professional, scientific, and technical services,” which include certifying agents, as those having annual receipts of less than \$17 million (13 CFR 121.201). There are currently 75 USDA-accredited certifying agents,<sup>24</sup> based on a query of the OID database, who provide organic certification services to producers and handlers. While many certifying agents are small entities that would be affected by this rule, we do not expect that these certifying agents would incur significant costs as a result of this action, as certifying agents already must comply with the current regulations (e.g., maintaining certification records for organic operations).

AMS concludes that this rule will not have any significant economic impact on small entities or affect a substantial number of small entities. The effect of this rule is that additional substances will be allowed in organic handling and organic crop production (low-acyl gellan gum and paper-based crop planting aids). The allowance of

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<sup>24</sup> USDA, Agricultural Marketing Service, Organic Integrity Database, Accessed June 9, 2022, <https://organic.ams.usda.gov/Integrity/>.

<sup>25</sup> Organic Trade Association (OTA), U.S. Organic Industry Survey 2021, available for purchase from <https://ota.com/market-analysis/organic-industry-survey/organic-industry-survey>.

these substances will provide entities, including small entities, with more options in their day-to-day operations.

### **Executive Order 12988**

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to the USDA to be accredited as a certifying agent, as described in OFPA (7 U.S.C. 6514(b)). States are also preempted from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of OFPA (7 U.S.C. 6503–6507).

Pursuant to OFPA (7 U.S.C. 6507(b)(2)), a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of OFPA, (b) not be inconsistent with OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to 7 U.S.C. 6519(c)(6), this rule does not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056) concerning meat, poultry, and egg products,

respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

### **Paperwork Reduction Act**

Routine collection, reporting, and recordkeeping related to the use of substances on the National List is included in NOP's approved information collection request (OMB control number 0581-0191). No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

### **Executive Order 13175**

This rule has been reviewed under Executive Order 13175 – Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments, or proposed legislation. Additionally, other policy statements or actions that have substantial direct effects on one or more Indian Tribes, the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes also require consultation.

After reviewing this rule, the Office of Tribal Relations (OTR) has determined that tribal consultation is not required. If a tribe requests consultation in the future, AMS will work with OTR to ensure meaningful consultation is provided.

### **Executive Order 13132**

Executive Order 13132 mandates that Federal agencies consider how their policymaking and regulatory activities impact the policymaking discretion of States and

local officials and how well such efforts conform to the principles of federalism defined in said order. This Executive order only pertains to regulations with clear federalism implications.

AMS has determined that this rule conforms with the principles of federalism described in Executive Order 13132. The rule does not impose substantial direct costs or effects on States, does not alter the relationship between States and the Federal Government, and it does not alter the distribution of powers and responsibilities among the various levels of government. States had the opportunity to comment on the proposed rule. No States provided public comment on the federalism implications of this rule. Therefore, AMS has concluded that this rule does not have federalism implications.

#### **Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

#### **General Notice of Public Rulemaking**

This rule reflects recommendations submitted by the NOSB to the Secretary to add two substances to the National List and updates the spelling of one substance on the National List.

#### **List of Subjects in 7 CFR Part 205**

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Livestock, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, AMS amends 7 CFR part 205 as follows:

#### **PART 205—NATIONAL ORGANIC PROGRAM**



1. The authority citation for 7 CFR part 205 continues to read as follows:

**Authority:** 7 U.S.C. 6501–6524.

2. Amend § 205.2 by adding, in alphabetical order, a definition for “Paper-based crop planting aid” to read as follows:

**§ 205.2 Terms defined.**

\* \* \* \* \*

*Paper-based crop planting aid.* A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in § 205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (*e.g.*, laboratory test using ASTM D6866 or composition review by qualified personnel).

\* \* \* \* \*

3. Amend § 205.601 by revising the introductory text and paragraph (o) to read as follows:

**§ 205.601 Synthetic substances allowed for use in organic crop production.**

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: *Provided*, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), (l), and (o) of this section, may only be used when the provisions set forth in § 205.206(a) through (d) prove insufficient to prevent or control the target pest.

\* \* \* \* \*

(o) Production aids.

(1) Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

(2) Paper-based crop planting aids as defined in § 205.2. Virgin or recycled paper without glossy paper or colored inks.

\* \* \* \* \*

4. Amend § 205.605 by:

a. In paragraph (a):

i. In the heading, removing the colon and adding a period in its place.

ii. Designating the entries as paragraphs (a)(1) through (30).

iii. Revising newly designated paragraph (a)(29).

b. In paragraph (b):

i. In the heading, removing the colon and adding a period in its place.

ii. Designating the entries as paragraphs (b)(1) through (36).

iii. Further redesignating newly designated paragraphs (b)(12)i. through iv. as paragraphs (b)(12)(i) through (iv).

iv. Redesignating newly designated paragraphs (b)(18) through (36) as paragraphs (b)(19) through (37).

v. Adding new paragraph (b)(18).

The revision and addition read as follows:

**§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”**

\* \* \* \* \*

(a) \* \* \*

(29) Waxes - nonsynthetic (Wood rosin).

\* \* \* \* \*

(b) \* \* \*

(18) Low-acyl gellan gum.

\* \* \* \* \*

**Erin Morris,**

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[FR Doc. 2022-24111 Filed: 11/10/2022 8:45 am; Publication Date: 11/14/2022]